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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,502	10/11/2001	Jerry G. Henslee	5972.US.P7	1118
23492	7590	04/06/2004	EXAMINER	
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/975,502	<b>Applicant(s)</b> HENSLEE ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments and Amendments***

1. Claims 2-4 and 6-8 are pending.  
  
Claims 6-8, drawn to non-elected inventions are withdrawn from examination.  
  
Claims 2-4 have been amended.  
  
Claims 1 and 5 have been cancelled.  
  
Claims 2-4 are examined on the merits.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. Applicants have amended the first line of the specification to reflect the current status of the parent applications.

### ***Withdrawn Objection***

#### ***Claim Objection***

4. Claim 4(c) is not longer objected to because the claim has been amended to correct the informality: The recitation "thepresence" now reads "the presence".

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 1 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of the claims.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 2-4 under 35 U.S.C. 102(b) as being anticipated by WO 98/21331 (May 22, 1998) and presented in the first action on the merits (FAOM) mailed September 23, 2003 is withdrawn. Claims 1 and 5 have been cancelled.

7. The rejection of claims 2-4 under 35 U.S.C. 102(e) as being anticipated by U.S. patent application publication US 2003/0059432 (filed July 13, 2001) and presented in the FAOM is withdrawn. Claims 1 and 5 have been cancelled.

***New Grounds of Objection***

***Sequence Compliance***

8. Figures 16, 18A and 18B within the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). These sequences have not been identified by SEQ ID numbers. This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With

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Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are requested to review the entire specification and amend it to include the sequence identifiers ensuring that these added SEQ ID numbers are not new matter.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claims 2-4 to recite method steps include the *detection of a combination of polypeptides*, the *contacting with two antibodies for each member of a combination of polypeptides*, and the *exposure of tissue section/cell culture to antibodies specific for each member of a combination of polypeptides*, respectively.

Applicants have also amended the claims to recite specific combinations of polypeptides, for example BS106 (SEQ ID NO: 8) and BU101 (SEQ ID NO: 6).

Applicants have not pointedly expressed in the Remarks/Arguments submitted January

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20, 2004 where in the specification support for these claim amendments can be found. Applicants can obviate the instant rejection by deleting the new matter or providing the page and line where support for the amendments is listed in the disclosure. If the new matter is deleted the 102(b) and 102(e) rejections set forth on pages 4 and 5 of the FAOM will be reinstated.

11. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 2 is vague and indefinite because it continues to recite an incomplete method step.

“Applicants submit that is irrelevant how the combination of polypeptides is detected...”. Applicants further aver that “[a]ny diagnostic method known to one of ordinary skill in the art may be utilized provided such method allows one to detect the presence [or] absence of both polypeptides of the combination”. These points of view have been carefully considered but found unpersuasive.

The claim continues not to recite a *complete* method. Applicants must present the claim in clear, concise and definitive language for one of ordinary skill in the art to clearly distinguish what is being claimed. Applicants are requested to provide all the components required for the implementation of the claimed method. While it is clear that that there is the detection of at least one polypeptide in a sample indicative of breast cancer the claims do not provide how the combination of polypeptides is

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detected. It is not clear what is the diagnostic tool used in the assay and the claim continues to be indefinite because it merely recites a use without all the required active and positive steps delimiting how the use is actually practiced.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent Application Publication number 2002/0009738 A1 (January 24, 2002). US patent application publication #2002/0009738 teaches Applicants' BS106 (SEQ ID NO: 8) and BU101 (SEQ ID NO: 6), which are the same as the publication's sequence 31 and sequence 77, respectively, see attached database sheets. These molecules are breast tumor proteins that may be detected in diagnostic methods, see abstract. A variety of biological samples may be tested, such as urine, a tumor biopsy sample, or a lymph node, see page 9, section 0139. The publication teaches that diagnosis of cancer can be performed and the change in the level of reactive polypeptide(s) evaluated, see page 9, section 0145.

The publication does not teach a method of detecting a combination of polypeptides in a test sample with at least two antibodies with the subsequent formation of antigen/antibody complexes of each member of said combination and resulting in the

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indication of breast cancer in a patient. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize antibodies in the detection of the taught breast tumor proteins in a patient sample within a tissue section or cell culture. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of the publication to detect two breast tumor proteins because the publication notes that "what is needed in the art is a methodology that employs the detection of two or more breast cancer specific genes in order to improve the sensitivity and reliability of detection of micrometastases, ", see page 1, section 0009. It would follow that the detection of encoded polypeptides would be useful in the diagnosis of breast cancer.



Page 8

Query Match 100.0%; Score 450; DB 9; Length 90;  
Best Local Similarity 100.0%; Pred. No. 5.1e-47;  
Matches 90; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

## RESULT 2

RESULT 2  
US-09-825-301-31  
; Sequence 31, Application US/09825301  
; Patent No. US20020009738A1

'18-09-975.

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> TITLE: NEW INVENTION:
; APPLICANT: Houghton, Raymond L.
; APPLICANT: Dillon, Davin C.
; APPLICANT: Molesh, David A.
; APPLICANT: Xu, Jiangchun
; APPLICANT: Zehentner, Barbara
; APPLICANT: Persing, David H.
; TITLE OF INVENTION: METHODS, COMPOSITIONS AND KITS FOR THE DETECTION
; TITLE OF INVENTION: AND MONITORING OF BREAST CANCER
; FILE REFERENCE: 210121.513
; CURRENT APPLICATION NUMBER: US/09/825,301
; CURRENT FILING DATE: 2001-04-02
; NUMBER OF SEQ ID NOS: 77
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 31
; LENGTH: 90
; TYPE: PRS
; ORGANISM: Homo sapien
US-09-825-301-31

Query Match          100.0%; Score 458; DB 9; Length 90;
Best Local Similarity 100.0%; Pred. No. 3.9e-37;
Matches 90; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY      1 MKFLAVLVLVLLGVSIFLVS AQNPTTAA PADTYPATGPADDEAPDAETTA AATTATTAAPT 60
Db      1 MKFLAVLVLVLLGVSIFLVS AQNPTTAA PADTYPATGPADDEAPDAETTA AATTATTAAPT 60

QY      61 ATTAASTTARKDIPVLPKWVGDL PNGRVCP 90
Db      61 ATTAASTTARKDIPVLPKWVGDL PNGRVCP 90

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***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however can normally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
05 April 2004